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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,338	09/19/2005	Reto Lerf	MEISS71.022APC	9313

20995 7590 09/26/2007

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EXAMINER	
YARNALL, MEGAN LEIGH	
ART UNIT	**PAPER NUMBER**
3709	

NOTIFICATION DATE	DELIVERY MODE
09/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/519,338	LERF, RETO	
	Examiner	Art Unit	
	Megan Yarnall	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/22/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *122204,040605*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 04/06/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance of some foreign language documents cited, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12, 13, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 12 and 25 recite the limitation "Material" in line 3. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 6-8, 10-12, 15-20, 24, and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Pilliar 3,855,638.

7. Re claim 1, Pilliar teaches an open-pored surface layer with a thickness in a range from 0.1mm to 2.5mm inclusive (col.4, ll.21-33) and the porosity of the open-pored surface layer is in a range from 20% to 80% (col.11, ll.1-2).

8. Re claim 6, Pilliar further teaches the surface layer wherein open-pored surface layer consists substantially of a material selected from the group consisting of titanium, zirconium, niobium or tantalum (col.2, ll.65-67).

9. Re claim 7, Pilliar further teaches the surface layer wherein the open-pored surface layer is sintered (col.8, ll.33-36).

10. Re claim 8, Pilliar further teaches a method of producing an implant comprising applying at least one layer of a biocompatible metal or an alloy thereof to a surface of the implant, to produce an implant surface (col.8, ll.9-38) and producing a surface micro-structure on the implant surface by means of application of fine biocompatible particles to the implant surface (col.4, ll.17-20).

11. Re claim 10, Pilliar further teaches a method wherein the biocompatible metal is applied by a technique selected from the group consisting of brushing, spreading, spraying, and a like application technique (col.8, ll.57-59).

12. Re claim 11, Pilliar further teaches a method wherein at the at least one layer applied to the virgin surface of the implant is sintered (col.8, l.60).

13. Re claim 12, Pilliar further teaches a method wherein materials are selected from the group consisting of binders, and sintering adjuvants (col.7, ll.29-32).

14. Re claim 15, Pilliar further teaches a method wherein sintering comprises a debindering phase (col.7, ll.37-40).

15. Re claim 16, Pilliar further teaches a method wherein a sintering temperature in the range of 1000°C to 1350°C is used (col.7, ll.49-51).

16. Re claim 17, Pilliar further teaches a method wherein the biocompatible metal is used in a powder form (col.4, ll.38-40).

17. Re claim 18, Pilliar further teaches a method wherein a layer thickness of the open-pored surface layer is in the range of 0.1mm-2.5mm (col.4, ll.21-33).

18. Re claim 19, Pilliar further teaches a method wherein the biocompatible metal applied to the surface of the implant has a particle size in the range from 50μm to 800μm (col.7, l.47).

19. Re claim 20, Pilliar further teaches a method wherein the biocompatible metal is selected from the group consisting of titanium, zirconium, niobium or tantalum (col.2, ll.65-67).

20. Re claim 24, Pilliar further teaches a method wherein the fine biocompatible particles are applied by a sol-gel method suing a binder (col.7, ll.29-32).

21. Re claim 26, Pilliar further teaches an implant having a surface layer according to claim 1 (col.5, ll.38-40).

22. Re claim 27, Pilliar further teaches using the implant for a hip implant (col.5, ll.38-40).

23. Re claim 28, Pilliar further teaches an implant is a joint replacement implant (col.5, ll. 38-40).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 1, 8, 11-14, 22, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Shimamune 5,034,186.

26. Re claim 1, Shimamune teaches a porous surface layer with a thickness in a range from 0.1mm to 2.5mm inclusive (col.4, ll.30-32). While Shimamune does not specifically disclose a porosity in the range of 20%-85%, or 30%-70%, or 35%-65%, it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

27. Re claim 8, Shimamune further teaches a method of producing an implant comprising applying at least one layer of a biocompatible metal or an alloy thereof to a surface of the implant, to produce an implant surface and producing a surface micro-structure on the implant surface by means of application of fine biocompatible particles to the implant surface (col.1, l.59-col.2, l.2, and col.4, ll.55-57).

28. Re claim 11, Shimamune further teaches a method wherein the at least one layer applied to the virgin surface of the implant is sintered (col.3, l.9).

29. Re claim 12, Shimamune further teaches a method wherein materials are selected from the group consisting of binders, and sintering adjuvants (col.2, l.67).

30. Re claim 13, Shimamune further teaches a method wherein as sintering adjuvant there is used a sintering adjuvant metal (col.2, ll.27-28) which, together with the biocompatible metal or alloy thereof, forms a low-melting eutectic (col.2, ll.28-44).

31. Re claim 14, Shimamune further teaches a method wherein sintering is carried out in vacuo (col.1, ll.66-68).

32. Re claim 22, Shimamune further teaches a method wherein the etching of the implant surface (col.2, l.20) is carried out by means of acid bath etching (col.3, ll.21-30).

33. Re claim 23, Shimamune further teaches a method wherein the fine biocompatible particles have a particle size in a range from 0.01μm to 5μm (col.4, ll.15-17).

34. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Branemark et al. 4,330,891. Pilliar teaches the invention as claimed and as discussed above. Pilliar does not teach a surface layer wherein the open pored surface layer has pits having a diameter in a range selected from the group consisting of the range from 0.1μm-2.5μm, 0.5μm-1.9μm, and 0.8μm-1.5μm.

Branemark teaches a surface layer wherein the open pored surface layer has pits having a diameter between 10nm and 1000nm (col.2, ll.38-40).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Pilliar in view of Branemark in order to improve operation results with pits approaching the order of magnitude of the cell diameter in the surrounding tissue as taught by Branemark, col.2, ll.17-19.

35. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Steinemann et al. 5,456,723. Pilliar teaches the invention as claimed and as discussed above. Pilliar does not teach a surface layer wherein the open pored surface layer has a shallow roughening in the sub-micrometer range.

Steinemann teaches a porous contact surface roughness of 2μm or less (col.3, ll.23-25).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Pilliar in view of Steinemann in order to make "the mating bone intergrow with the implant along the contact surface and speedily form a strong and durable bond as taught by Steinemann, col.3, ll.20-23.

36. Claims 4, 5, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimamune 5,034,186 in view of Hall 2002/0038149. Shimamune teaches the invention as claimed and as discussed above. Shimamune does not teach a surface layer comprising biocompatible particles arranged on the implant surface, the particles selected from the group consisting of titanium dioxide and calcium phosphate.

Hall teaches an implant surface layer comprising calcium phosphate (par.44, ll.1-3).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shimamune in view of Hall in order to combine "properties for rapid bone growth during the early healing phase with the long term stability during clinical loading conditions" as taught by Hall, par.44, ll.3-6.

37. Re claim 5, Shimamune further teaches a surface layer wherein the biocompatible particles have a particle size in a range from 0.01μm to 5μm (col.2, ll.54-58 and col.4, ll.16-17).

38. Re claim 25, Shimamune teaches the invention as claimed and as discussed above. Shimamune does not teach a method wherein a surface layer comprising biocompatible particles arranged on the implant surface, the particles selected from the group consisting of titanium dioxide and calcium phosphate.

Hall teaches an implant surface layer comprising calcium phosphate (par.44, ll.1-3).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shimamune in view of Hall in order to combine "properties for rapid bone growth during the early healing phase with the long term stability during clinical loading conditions" as taught by Hall, par.44, ll.3-6.

39. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Shimp 2001/0031799. Pilliar teaches the invention as claimed and as discussed above. Pilliar does not teach a method wherein the biocompatible metal is applied by means of a vacuum plasma spraying method.

Shimp teaches a coating applied to an implant by means of a vacuum plasma spraying method (par.13, l.7).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Pilliar in view of Shimp in order to produce very fast heating or cooling as taught by Shimp, par.13, l.4.

40. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Pilliar 4,206,516. Pilliar teaches the invention as claimed and as discussed above. Pilliar '638 does not teach a method wherein the biocompatible metal is used in the form of a metal hydride powder.

Pilliar '516 teaches a method wherein the biocompatible metal is used in the form of a metal hydride powder (col.2, ll.46-49).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Pilliar '638 in view of Pilliar '516 in order to provide a thermally decomposable compound as taught by Pilliar '516, col.2, ll.50-51.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Yarnall whose telephone number is 571-270-3071. The examiner can normally be reached on Monday-Thursday 6:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on 571-272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Megan Yarnall
September 18, 2007

EHUD GARTENBERG
SUPERVISORY PATENT EXAMINER
9/19/07